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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,319	09/18/2002	Mary K. Crow	5983/IG123-US2	1541

7590

05/04/2006

Darby & Darby  
805 Third Avenue  
New York, NY 10022-7513

EXAMINER
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GAMBEL, PHILLIP

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 05/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/088,319	Applicant(s) CROW ET AL.	
	Examiner Phillip Gambel	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 February 2006.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-9 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. Applicant's election of Group I, claims 1-3, filed 2/3/06, for prosecution with traverse is acknowledged.

Upon a review of applicant's reasons, filed 2/3/06, in view of the teachings of Schubert et al. with respect to the substitution of a C for the A at position -125 from the transcription start site; the inventions of Groups I-V would have a special technical features that defines a contribution over Schubert et al., J. Biol. Chem 270: 29624-29627, 1995 as set forth in PCT 210 Search Report and indicated on the IDS, filed 3/13/02, of record.

However, upon an updated search in view of applicant's arguments concerning Schubert et al. of record, the following references are provided to indicate that applicant's inventions of Groups I-V do not define a contribution over the prior art.

Given applicant's traversal, this Office Action is set forth to provide applicant an opportunity to respond to the newly cited prior art.

The examiner apologizes for any inconvenience to applicant in this matter.

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Group I. Claims 1-3, drawn to a nucleic acid, vector and host cell.

Group II. Claim 4, drawn to a method of identifying an individual at risk by sequencing a segment of a promoter sequence.

Group III. Claims 5-7, drawn to a method of identifying an individual at risk by measuring the level of transcriptional activity.

Group IV. Claim 8, drawn to a method of identifying a compound that is useful in treating by contacting a CD40L promoter sequence.

Group V. Claim 9, drawn to a method of identifying a compound that is useful in treating by contacting a reconstituted system.

3. The inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

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The invention of Group I was found to have no special technical feature that defined the contribution over the following prior art.

Li et al. (Arthritis and Rheumatism 42(6): 1291-1296, 1999) the same or nearly the same altered nucleotide sequence in the immediate promoter region of CD40 ligand is associated with rheumatoid arthritis (see Abstract) as encompassed by the instant claims.

Applicant is invited to provide the public availability date of co-inventors disclosure for the 63<sup>rd</sup> Annual Scientific Meeting of the American College of Rheumatology and the 34<sup>th</sup> Annual Scientific Meeting of the Association of Rheumatology Health Professionals, Boston Massachusetts, 1999.

For example, applicant is invited to address whether publications were made available to the public prior to the Meeting as well as at the Meeting itself.

Gomoloka et al. (J. Mol. Med. 73: 19-29, 1995) teach various genes associated with increased risk to develop rheumatoid arthritis in difference groups of adult patients (see entire document, including Abstract, Table 1, Figure 1).

MacDonald et al. (J. Clin. Invest. 100: 2404-2414, 1997) teach the isolation of nucleic acids encoding CD40L expressed by T cells in rheumatoid arthritis (see entire document, including Methods and Results)

Given the association of the claimed altered CD40L promoter with rheumatoid arthritis, the prior art teachings of isolating nucleic acids encoding CD40L in rheumatoid arthritis patients would anticipate or render obvious the claimed nucleic acids having the sequence of residues 331-455 of SEQ ID NO:2. One of ordinary skill would have been motivated to isolate nucleic acids encoding CD40L, including the regulatory regions, in order to determine structural or functional aspects of CD40L regulation in arthritis, given the contribution of CD40L to the inflammatory aspects of the disease. Such information would have been important to the ordinary artisan at the time the invention was made in the diagnosis and treatment of arthritis patients as well.

For examination purposes, the term "having" is being interpreted as being inclusive or open - ended which does not exclude additional unrecited elements, provided that the additional elements do not materially affect the basic and novel characteristic(s)" of the claimed invention.

Further, it does not appear that applicant's priority document 60/153,615 provides sufficient written description for the breadth of the claims, as currently recited.

Under 35 USC 120, a claim in a U.S. application is entitled to the benefit of the filing date of an earlier filed U.S. application if the subject matter of the claim is disclosed in the manner provided by 35 USC 112, first paragraph in the earlier application. See MPEP 201.11.

Applicant is reminded that a claim as a whole has only one effective filing date.

See e.g. Studiengesellschaft Kahle m.b.H. v. Shell Oil Co. 42 USPQ2d 1674, 1677 (Fed. Cir 1997)

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4. Accordingly, Groups I-V are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

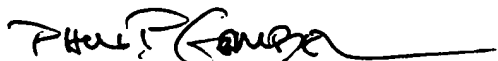
5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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May 1, 2006